MAY 3 1 2005

K050638

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510(K) Summary

Date Summary Prepared: March 8, 2005

Lenstec, Inc.
510(k) Premarket Notification Submission
Lenstec Injector System for Tetraflex™ Intraocular Lenses
510(K) Premarket Notification Summary

Trade/Device Name: Lenstec Injector System for Tetraflex™ Intraocular Lenses
Regulation Number: 21 CFR 886.1850
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS

Labeling:
Federal (United States) Law restricts this device to sale by or on the order of a physician.

1. Applicant Information:
   a. Name: Lenstec, Inc.
   b. Address: 2870 Scherer Drive, Suite 300
      St. Petersburg, FL 33716
      Telephone Number: 727 571-2272
      Fax: 727 571-1792
   c. Contact Person: Luis A. Ruiz, Vice President, Quality Assurance
   d. Address: 2870 Scherer Drive, Suite 300
      St. Petersburg, FL 33716
      Telephone Number: 727 571-2272
      Fax: 727 571-1792
      Email: lruiz@lenstec.com

2. Name of Device:
   a. Trade Name: Lenstec Injector System for Tetraflex™ Intraocular Lenses
   b. Common Name: Intraocular lens guide.
   c. Classification Name: Folders and injectors, intraocular lens (IOL) (MSS, 886.4300)

3. Substantially Equivalent legally-marketed devices:
    a. Medicel MultiJect Injector for IOLs and MicroGlide Cartridge K040837, June 17, 2004.
    b. STAAR Surgical Foam Tip™ Injector System K980696, Sept 11, 1998.

4. Device Description:
The system consists of the following components:

Cartridge	Injector	Nominal Incision Size (mm)	Used with Tetraflex™ Intraocular Lenses Power Range (D)
LC604220	I 9000	2.8	5.0 – 36.0
LC604240 W/LS604500	I 9007	2.2	5.0 – 26.0

Two types of injectors are provided: both injectors are syringe based and are reusable and autoclavable. The cartridges/silicone cushion are single-use and provided sterile.

5. Use:
The Lenstec Injector System is to be used solely to insert the foldable Tetraflex™ intraocular lenses manufactured by Lenstec and is used in conjunction with the Medicel cartridges, MicroGlide LC604220 and ViscoGlide LC604240 (w/Silicone Cushion LS604500).

6. Indications for use:
The Lenstec IOL Injection system is intended for use in implantation of the Lenstec Tetraflex™ Accommodating Posterior Chamber Intraocular Lens into the capsular bag following extracapsular extraction.

7. Technological characteristics:
The primary system has two major components: a reusable injector and a disposable cartridge LC604240. A secondary system also has three major components: a reusable injector and a disposable cartridge LC604220 and includes the use of a Silicone Cushion supplied with the LC604220 cartridge.
    a. The injector is manufactured of titanium and can be autoclaved.
    b. The cartridge is manufactured of lubricated polypropylene and is Single Use.
    c. The silicone tip is manufactured of medical grade polypropylene body and a silicone tip and also is Single Use.

8. Performance data:
    a. Non-clinical tests
    All contact materials have been tested for biocompatibility. The system was tested with Tetraflex™ intraocular lenses.

9. Clinical tests:
Not required

10. Conclusions

The Lenstec Injector System with MicroGlide cartridges are substantially equivalent in safety and efficacy to the legally marketed predicate device.

Luis A. Ruiz
Vice President, Quality Assurance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2005

Lenstec Inc.
c/o Mr. Luis A. Ruiz
Vice President, Quality Assurance
2870 Scherer Drive, suite 300
St. Petersburg, FL 33716

Re: K050638
Trade/Device Name: Lenstec Intraocular Lens (IOL) Injection System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: May 12, 2005
Received: May 13, 2005

Dear Mr. Ruiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html..

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K050638

Device Name: Lenstec Intraocular (IOL) Lens Injection System

Indications For Use: The Lenstec IOL Injection System if intended for use in implantation of the Lenstec Tetraflex™ Accommodating Posterior Chamber Intraocular Lens into the capsular bag following extracapsular extraction.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K050638